Software User Manual

Field Maintenance Software Version 5.0

MedSystem III® Infusion Pump
Model 286X

CardinalHealth

Alaris® Products
June 2006

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FIELD MAINTENANCE SOFTWARE (CONTINUED)

APPENDIX

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Introduction

Product Notification:

- Documentation provided with this product may reference product(s) not present in your facility or not yet available for sale in your area.
- Field Maintenance Software (FMS) User Manual is designed to assist Biomedical personnel in customizing the MedSystem III® infusion pump (instrument) to meet special needs of their institutions.
- Main text discusses different features of FMS and how to initiate them. Appendices provide additional information for instrument Configuration, Calibration, and Log Menu pages.
- All KEY NAMES are written in regular type as they appear on instrument or computer keyboard. All SCREEN MESSAGES are as they appear on screen, except they are in *italic* type, and Menu Titles are in regular type with only first letters capitalized.
- For more information on other MedSystem III® infusion pump features, refer to instrument Directions for Use (DFU).

About FMS

This software is provided under and subject to a license from Cardinal Health.

Presented herein is a detailed description of FMS, a program that runs on a personal computer (PC) running Windows 2000 or Windows XP. This program assists organizations in servicing and customizing configuration of instrument. This manual is to be used only with instrument software versions 4.0 or higher.

Warnings and Cautions

A **WARNING** is an alert to a potential hazard which could result in serious personal injury and/or product damage if proper procedures are not followed.

A **CAUTION** is an alert to a potential hazard which could result in minor personal injury and/or product damage if proper procedures are not followed.

WARNINGS

- At no time should FMS be used to configure instrument while it is connected to a patient.
- Ensure instrument is in operational status before returning it to patient use.
- FMS version 5.0 is not compatible with instrument software versions 3.0 and 3.5

CAUTIONS

Hospital policies and procedures should be consulted when determining appropriate air-in-line thresholds. As a general guideline, set lowest thresholds appropriate when patient susceptibility to infused air is an important consideration.

Software Revision Highlights

Below are examples of differences between FMS Dos version 2.24 and FMS Windows version 5.0. User interface changes have also occurred due to differences in systems.

DOS	Windows
If more than one configuration function is executed, FMS prompts user to save a configuration file. If only one function is executed FMS will NOT prompt user to save a configuration file.	If one or more configuration function is exectued, FMS prompts user to save configuration file.
User can not change directory when saving a file.	User can choose which directory to save file in.
An option is selected either by using up or down arrow keys on computer keyboard to highlight desired option, or by typing first character of desired option (such as L to select Logs Menu).	An option is selected by clicking it with mouse.
A selected option is executed by pressing enter key.	A selected option is executed by clicking ok button on screen with mouse.
No delay in establishing and ending communications between instrument and computer.	A slight delay in establishing and ending communications between instrument and computer due to a more robust communication method.
Navigating menu items can only be accomplished when establishing communication with instrument.	Navigating menu items can be accomplished with or without establishing communication with instrument.
2 COM port options available, COM1 and COM2.	8 COM port options available, COM1 through COM8.
Reports are navigated using only up or down arrows.	Reports are navigated using horizontal and vertical scroll bars.

Abbreviations / Acronyms

CIDLIP	Cassette Indentification/Latch in Place
ClrAir	Clear Air
COM	Communications
CP	Controller Pressure
DRC	Dose Rate Calculator
FMS	Field Maintenance Software
GP	General Purpose
GP2	General Purpose II
GPII	General Purpose II
IBM	International Business Machines
ID	Identification
KVO	Keep Vein Open
LCD	Liquid Crystal Display
NN	Neonatal
NiCd	Nickel Cadmium
OR	Operating Room
OR2	Operating Room II
ORII	Operating Room II
PC	Personal Computer
PSOD	Patient Side Occlusion Detection
vol	Volume
VR	Volume Remaining

Commands / Definitions

With FMS, user can customize configuration of instrument from a menu of parameters. User highlights a selected *Configuration Command* on Instrument Configuration Command Menu, and then places instrument in Maintenance Mode by following directions on screen.

This list of commands will be displayed as follows:

00 *Reset Faults* - Allows pump channel to be reset from Service to an operational status.

01 *Clear Log* - Allows user to clear all entries in internal Event, Status, or Alarm Log.

02 *Reset Rate, Volume Remaining, Time Remaining* - Resets rate, VR, and time remaining to factory default settings. This should be used in event of a Watchdog (30,x) Range Error.

03 *Set Instrument Serial Number* - Allows user to enter instrument serial number for display on User Information and Instrument Settings pages.

04 *Set User Information Line* - Allows an institution to enter their ID number, code, or name for display on User Information page. Limited to 25 characters including spaces.

05 *Enable/Disable Special Notes* - Allows user to enable/disable Special Note page feature.

06 *Set Date To Display Special Note* - Allows user to set date for Special Notes page. Page displays every time instrument is turned on.

07 *Set Special Note Messages* - Allows user to enter up to five lines of text, 27 characters per line including spaces on Special Notes page.

08 *Clear Main Battery Date* - Allows main battery installation date and Battery Log to be cleared.

09 *Clear Backup Battery Date* - Allows only backup battery installation date to be cleared.

10 *Reset Device Specific Parameters* - Automatically resets all device type specific parameters in instrument to factory default values.

11 *Enable/Disable ClrAir Softkey* - Allows user to enable/disable ClrAir softkey for a specific device type.

12 *Change Rate Breakpoint for ClrAir* - Allows user to set a specific device type and specific Clear Air rate breakpoint, below which ClrAir softkey is not available.

13 *Lock/Unlock Dose Rate Calculator* - Allows user to lock out Dose Rate Calculator feature.

14 *Set KVO Rate for Device Type* - Set Keep Vein Open (KVO) Rate for a specific device type, which occurs following an Infusion Complete Advisory.

Commands / Definitions (Continued)

15 *Set Maximum Rate for Device Type* - Set maximum limit for Primary infusion rates for a specific device type.

16 *Set Maximum VR for Device Type* - Set maximum limit for Primary VR for a specific device type.

17 *Set Max Secondary Rate for Device* - Set maximum limit for Secondary infusion rates for a specific device type.

18 *Set Max Secondary VR for Device* - Set maximum limit for Secondary VR for a specific device type.

19 *Enable/Disable Audio Ramping* - Allows automatic ramping of alarm audio volume to be enabled or disabled when alarms are ignored.

20 *Set Instrument Off Delay* (1, 3, 5, 10 seconds) - Allows user to set period of time that OFF key must be pressed and held to turn off instrument.

21 *Set Main Battery Install Date* - Allows instrument's memory to maintain date NiCd battery pack was last changed.

22 *Set Backup Battery Install Date* - Allows instrument's memory to maintain date memory-backup battery was last changed.

23 *Set Fractional Scrolling Breakpt* - Allows user to set breakpoint at which VR and Rate change from increments of tenths of a milliliter (0.1) to increments of 1 milliliter (1.0) (for General Purpose II and Operating Room II device types only).

24 *Lock/Unlock Device Type Change* - Allows instrument to be locked in current device type.

25 *Lock/Unlock IVPB* - Allows all three channels to be locked in current channel mode (such as, Basic, Dual Rate).

26 *Enable/Disable ALL Setting for VR* - Allows a channel to infuse until container is empty, rather than infusing a set volume remaining (VR) (applicable for Operating Room and Operating Room II device types only).

27 *Set Air-in-Line Alarm Sensitivity* - Set threshold at which an Air-in-Line alarm occurs for a specific device type.

28 *Set Pressure Increment* - Set incremental pressure over baseline at which a Patient-side Occlusion alarm occurs for a specific device type.

29 *Set Maximum Pressure* - Sets maximum pressure at which a Patient-side Occlusion alarm occurs.

30 *Lock/Unlock Dose Parameters* - Allows user to access and change drug concentration and dose rate units for all drugs.

31 *Reset Instrument Configuration Data* - Automatically resets non-device type specific instrument configuration parameters to factory default settings, including rate, VR and time.

Instrument Programming and FMS Functions

Instrument Programming

Programming Menu is available from Main Menu by highlighting Instrument Programming. The following selections are displayed:

- *Dose Rate Calculator* - Allows user to select and program a Dose Rate Calculator Drug Table configuration to an instrument.
- *Batch Programming* - Allows user to execute a set of configuration commands by selecting a Batch Programming file, then reviewing and executing sequential commands in file.
- *Quit Programming* - Returns user to Main Menu.

Calibration Functions

Calibration data can be stored, displayed, or printed by using appropriate FMS commands.

Calibration operations provided by FMS:

- Full Calibration (all channels)
- Cassette/Latch Sensor Calibration (all channels)
- Patient-Side Occlusion Calibration (all channels)
- Fluid-Side Occlusion Calibration (all channels)
- Single Calibration Menu (single channel)
- Calibration Data Menu
- Full Calibration Information
- Quit Calibration

Instrument Programming and FMS Functions (Continued)

Event, Alarm, and Status Log Function

Logs Menu functions provided by FMS:

- Retrieves Event, Status, Alarm, or All Logs from instrument and stores it to a file
- Displays Event, Status, Alarm, or All Logs from either instrument or a file
- Prints Event, Status, Alarm, or All Logs from a file

Other FMS Functions

- Obtains on-line help information at any time by pressing F1 key
- Displays available commands when F3 key is pressed (under Instrument Configuration)
- Displays parameter ranges and units when F4 key is pressed (under Instrument Configuration)
- Selects desired communication port (COM1 through COM8)
- Recognizes critical errors and issues prompts to process them
- Recognizes disk full errors and prompts user accordingly. An empty disk can be inserted and operation repeated
- Recognizes old instrument communications protocol (version 3.5 and earlier)

NOTE: During FMS operation, Control C input from keyboard is ignored.

Installation and Setup

System Requirements

FMS uses a PC serial communications (COM) port to communicate with an instrument.

Hardware

- IBM-PC or compatible with a minimum of 512K memory
- CD ROM Drive
- Serial port (COM1 through COM8)
- EGA, CGA, or VGA display
- 9- to 25-pin (female to male) adapter (as needed)
- Serial to USB adapter (as needed) (See note below)
- Printer (optional)

NOTE: If using a serial to USB adapter, because no serial port is available, Windows will assign a COM port number. If assigned number is higher than 8, consult the adapter documentation to reassign the port number.

Software

- Microsoft Windows 2000 or Windows XP Operating System. Use of one of these operating systems is required to provide necessary support.
- Field Maintenance Software (FMS) version 5.0

Software Installation

Unpacking FMS Kit

FMS kit should contain following items:

- RS-232 cable with 7-pin connector (optional)
- Field Maintenance Software CD ROM

Installing Software

This CD contains the following:
Adobe Acrobat Reader 6.0.1
FMS Application Software
FMS Directions for Use

Accessing the Directions for Use*

The DFU can be opened directly from the CD or from within Adobe Acrobat Reader.

Access from the CD

1. On the CD locate the DFU PDF file in the FMS folder.
2. Double click on the file to open it.
3. If desired, save file to directory of choice.

Access from Adobe Acrobat Reader

1. Select [File] from the menu, then select [Open].
2. Navigate to the FMS folder on the CD using the [Open] dialog [Look in] option.
3. Select the DFU file, then [Open].
4. If desired, save file to directory of choice.

Accessing the FMS Application

The FMS application can be run from the CD. It is, however, recommended that the application be run from the Hard Drive.

1. On the CD locate the FMS folder. The following files are in the folder:
   - DRUGDEFT.SET
   - FMS.EXE
   - X40DA.RL
   - X40DE.RL
   - X40DS.RL
2. Copy the FMS folder to directory of choice on Hard Drive.

***If Adobe Acrobat 6.0.1 is needed, see text file in "Adobe Acrobat 6.0.1" folder.**

NOTE: Icon associated with FMS.EXE will be displayed in directory where FMS is located, in task bar when FMS is in use, and as the shortcut icon.

Cable Hookup

Connect special 7-pin connector on serial cable to COM port on side of instrument. Connect 25-pin connector end to selected COM port of PC. If PC uses a 9-pin connector, use a 9- to 25-pin (female to male) adapter.

Turn instrument on in Maintenance Mode by simultaneously pressing ON/OFF and MORE OPTIONS keys. LCD should now read *Maintenance* and indicate current device type. Instrument is now ready for FMS.

Uninstalling Software

CAUTION

Software uninstall program automatically and permanently deletes unsaved data. To avoid this, save any unsaved data before uninstall procedure is performed.

1. Select **Start ▶ Settings ▶ Control Panel**.
   - Control Panel window opens.
2. Double-click **Add or Remove Programs**.
3. Select **FMS**.
4. Click **Remove**.
5. Follow prompts to complete uninstall procedure.

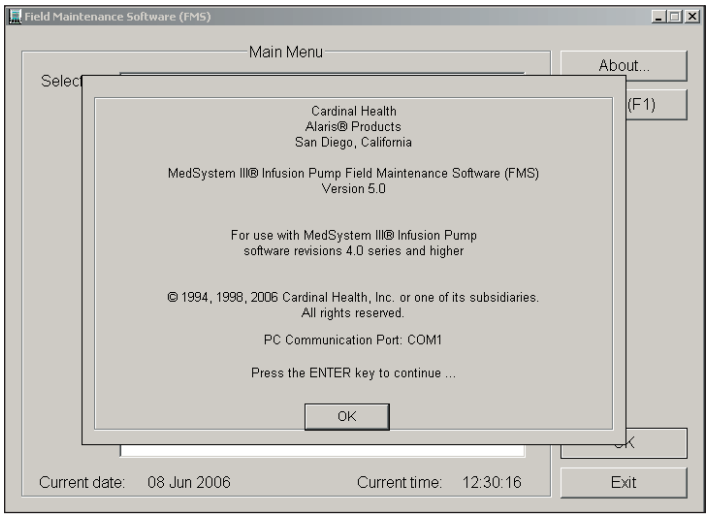
Checking Installed Software Version

Select **About Button** from main menu.

- **About** box opens.
- To close about box press enter or click **OK**.

> **NOTE:** 5.0 in illustrated display represents current software version.

About FMS Software Version



Starting FMS

General Information

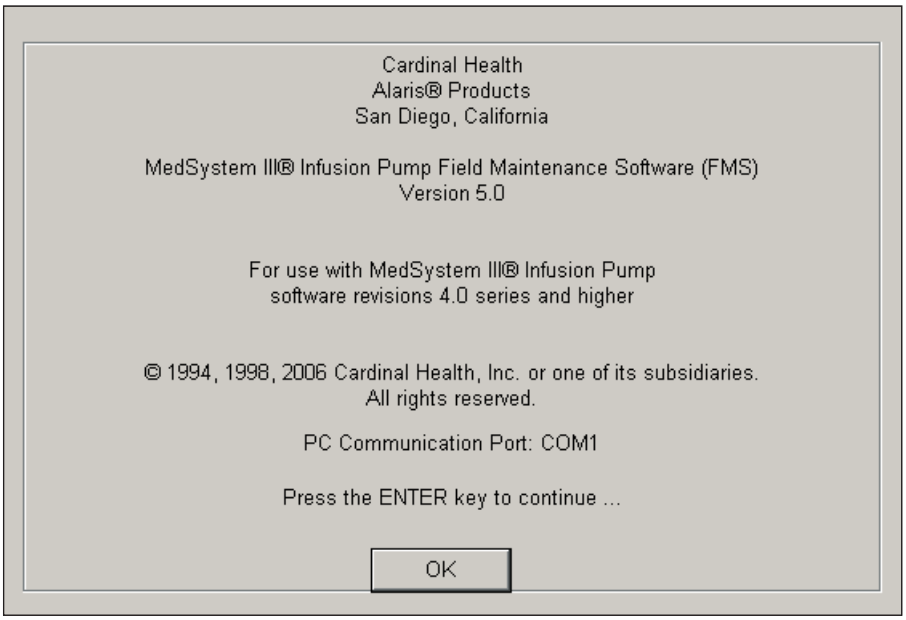
Running FMS

To open FMS, select FMS shortcut on desktop.

OR

Select Start ► Programs ► Alaris Products ► FMS v5.0 ► Title Page opens.

Title page

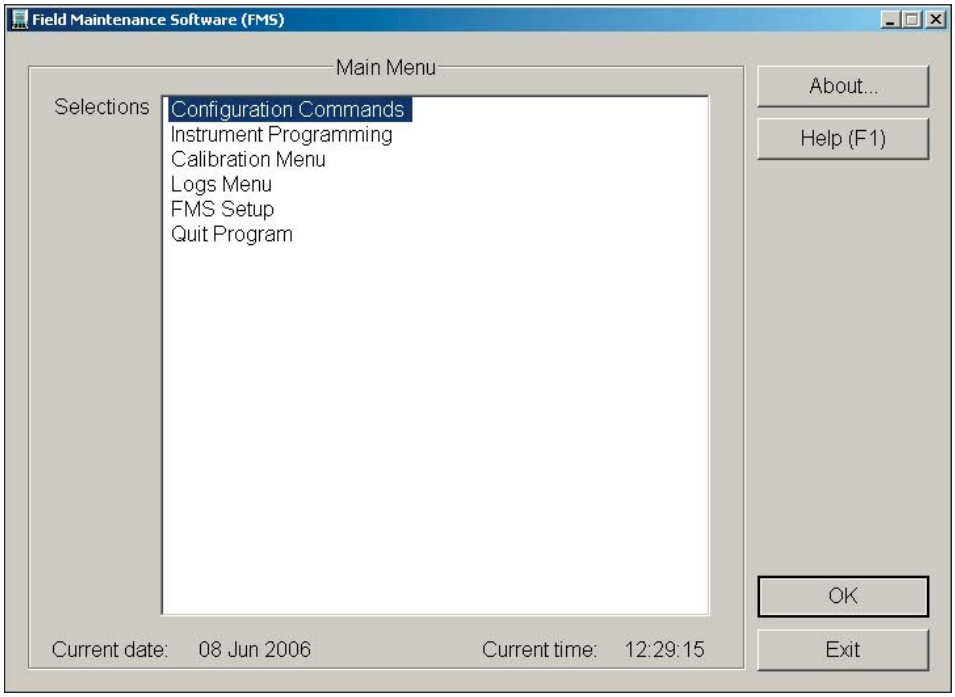


Verify software, version appearing on Title Page is correct, press enter or click **OK** to bring up FMS Main Menu functions. Serial port information will also be displayed on title page.

> **NOTE:** Date and time set on the computer are used by FMS when storing instrument Logs and Calibration Data, so it is important that these values are correct.

Main Menu Options

Main Menu



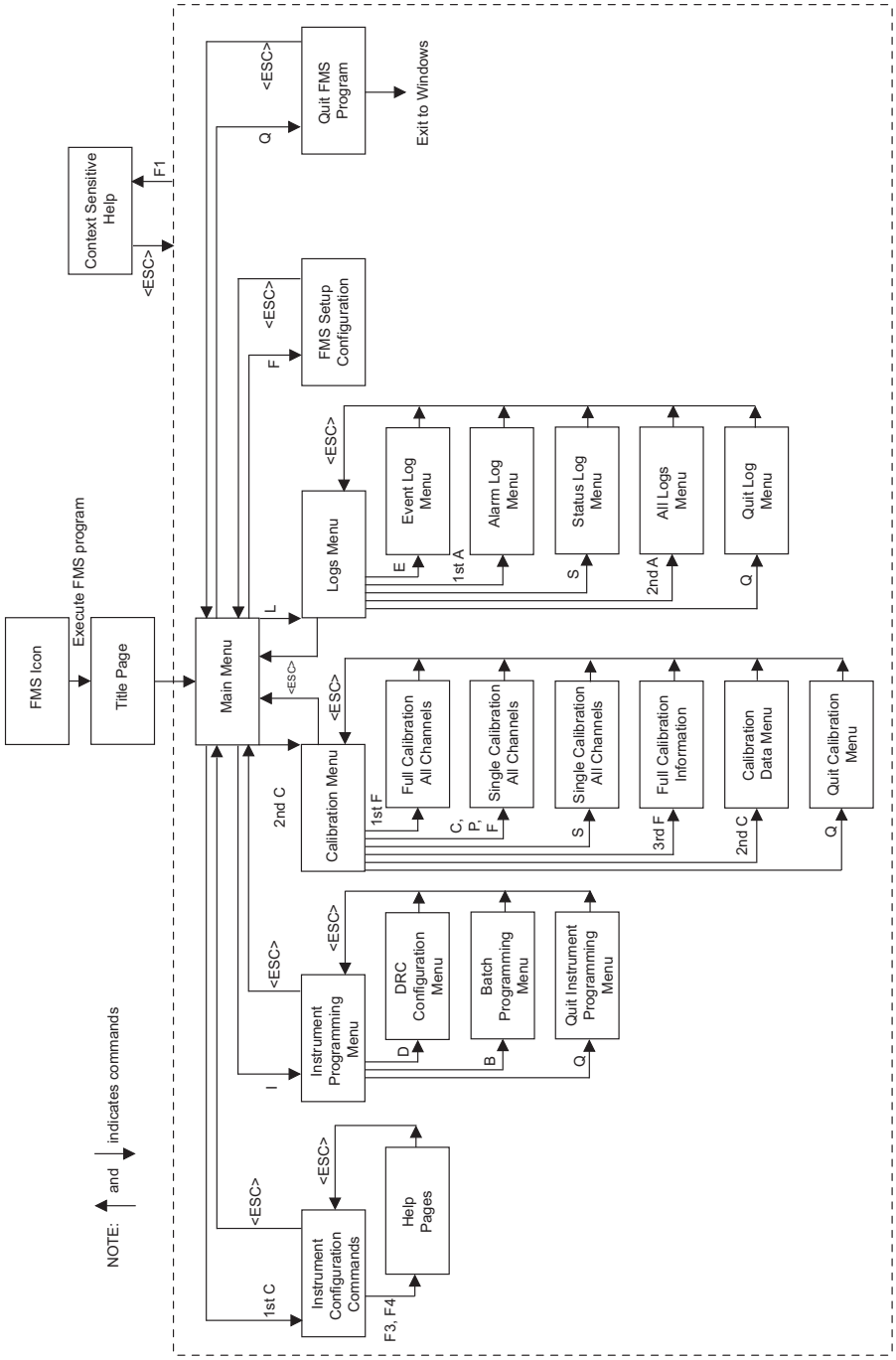
Verify date, time on Main Menu are correct. If date or time are incorrect, exit by executing Quit Program option on FMS Main Menu. Then set correct date/time on computer.

An option is selected either by using up and down arrow keys on computer keyboard to highlight desired option, by typing first character of desired option (such as, ***L*** to select Logs Menu), double clicking on menu item or highlighting item and clicking OK.

To execute selected option, press Enter key. If there are two options having same first character, they will be alternately selected when key is pressed (such as, first ***C*** will select Configuration command; second ***C*** will select Calibration menu).

For an overall program flow of FMS, refer to “Overall Program Flow of FMS” figure.

Overall Program Flow of FMS



Serial Port Setup

- FMS is provided with COM1 as default communications port.
- FMS remembers last port used.
- FMS attempts to establish communication with last port used. If instrument is not connected to that port, FMS Setup option on Main Menu must be used to select new port.
- To switch between communication ports, use FMS Setup option on Main Menu.

Serial communications ports are chosen randomly, if computer has more than 8 ports use Windows setup options to set one port as COM port to communicate with instrument.

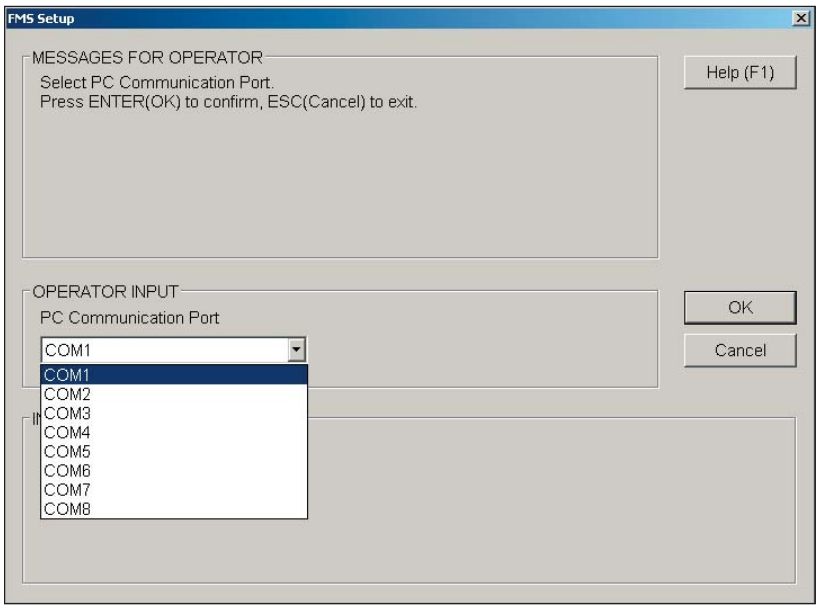
> **NOTE:** To establish communication, port to which instrument communication cable is connected must match port selected through FMS.

- When starting FMS, Title page will indicate last port used.

Select FMS Setup Screen from Main Menu.

Current communication port configuration will be displayed. Select port and then confirm selection.

FMS Setup Screen



During an FMS session, if software cannot make connection with a COM port, user will be prompted with message, *Instrument is off or cable is not connected to right port.*

General Page Layout

After an item is selected from Main Menu the display will switch screens for selected item. Screen for each item is divided into the following four sections:

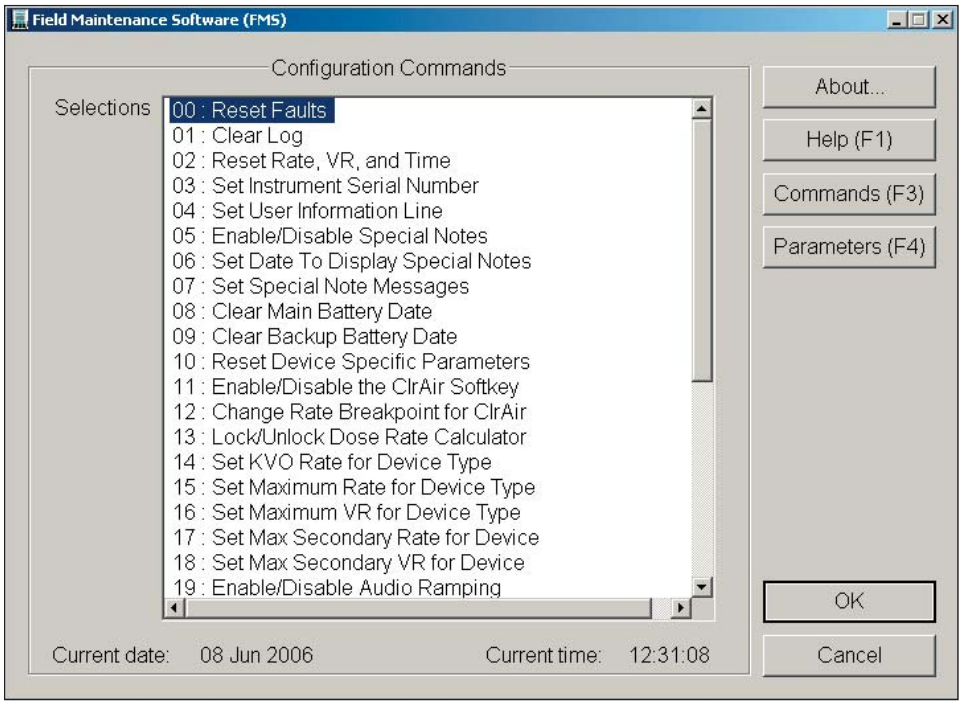
SELECTION - Indicates currently highlighted function.

MESSAGES FOR OPERATOR - Guides operator through use of given function, and provides instructions in case of errors.

OPERATOR INPUT - Shows what user entered via computer keyboard.

INSTRUMENT RESPONSE - Shows response of instrument to a certain command by operator. A "successful" response indicates that command was accepted. If command is not accepted, appropriate error message will be displayed.

Instrument Configuration Screen

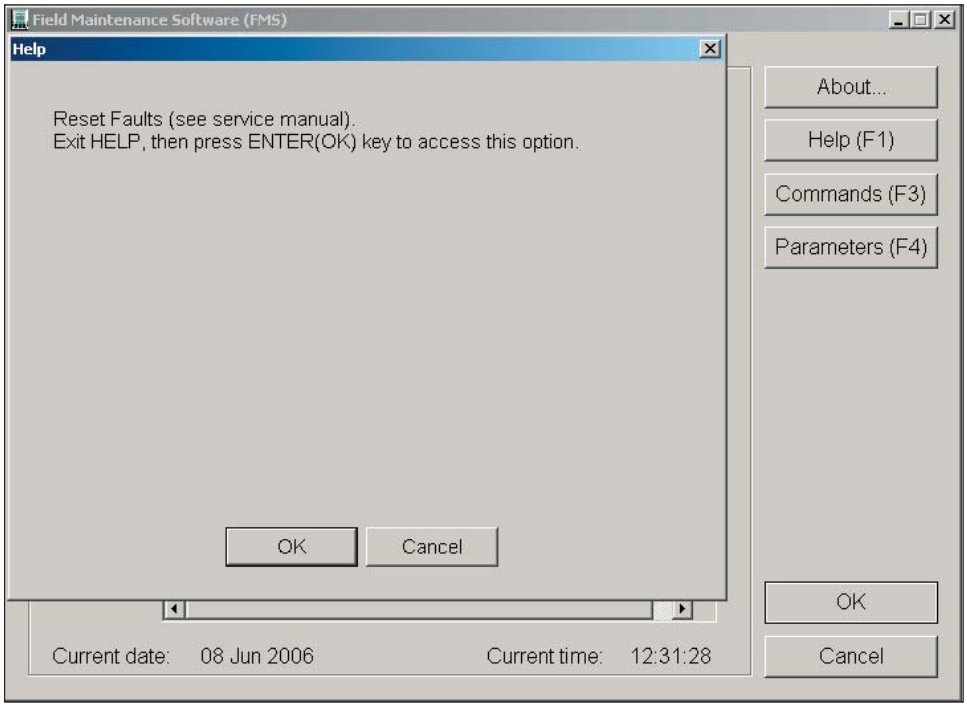


On-line Help

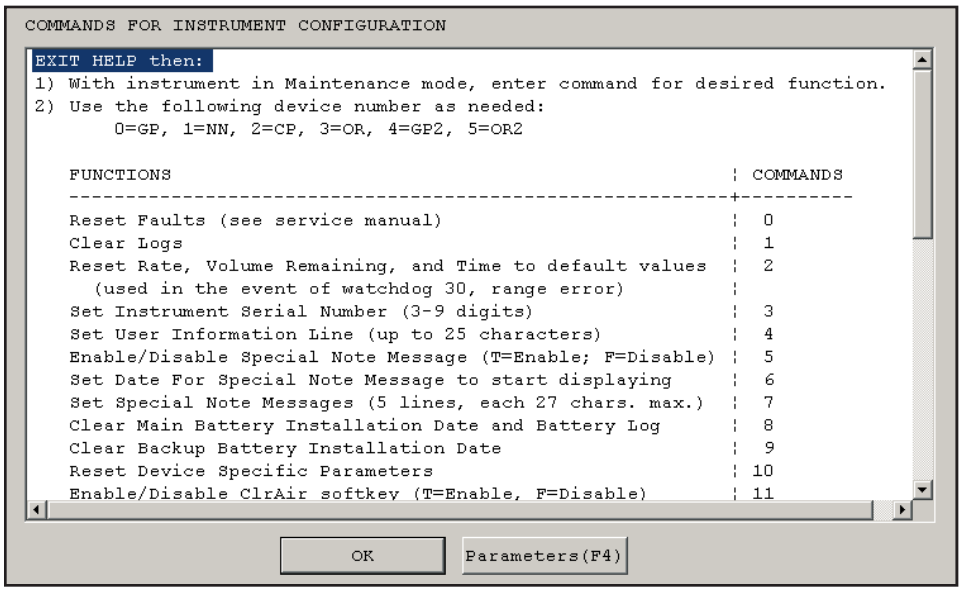
• On-line HELP is available in FMS by using F1 key or by clicking help button on right side of screen, as depicted in “Context Sensitive Help Example” figure. Help box will pop up in center of screen and outlines what command will do. This help option is only available at menu levels.

• Use F3 key for User Summary information regarding available commands in Instrument Configuration mode. Use F4 key to display a table of allowable parameter ranges. For a complete display of Summary Information screens, see “Usng Summary Information in Instrument Configuration Commands Using F3 key”, “Parameter Ranges and Units Using F4 Key ” figures .

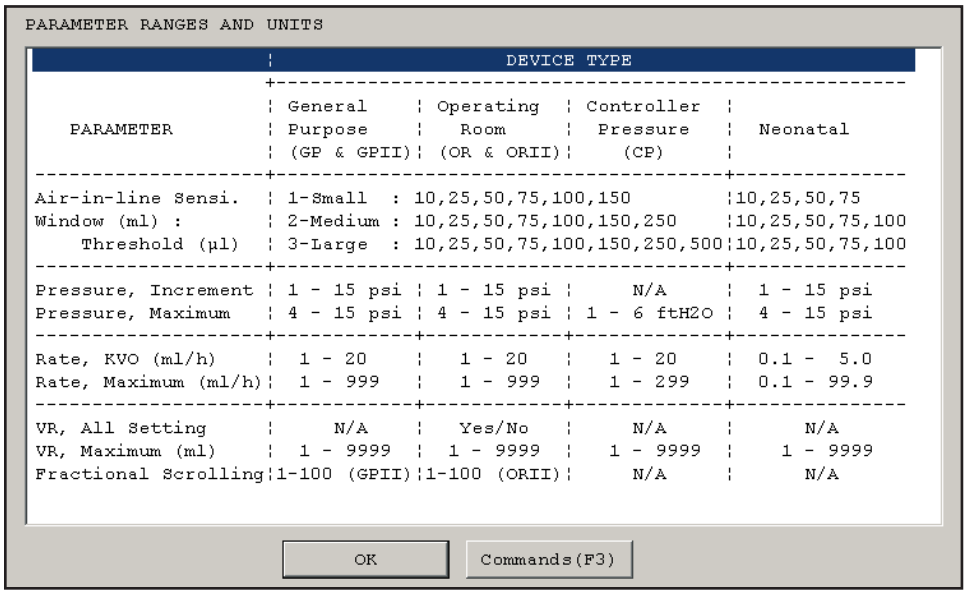
Context Sensitive Help Example



Using Summary Information in Instrument Configuration Commands Using F3 Key



Parameter Ranges and Units Using F4 Key



Automatic Maintenance Mode Recognition

At start of an operation that requires communication with instrument, FMS automatically checks to see if instrument is in Maintenance Mode. If not, FMS display prompts user to put instrument in Maintenance Mode.

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Customizing Parameters: Instrument Configuration Mode

Instrument parameters can be customized using Instrument Configuration Mode. For FMS to set instrument parameters described in this section, instrument must be in Maintenance Mode.

To place instrument in Maintenance Mode, turn instrument on by simultaneously pressing ON/OFF and MORE OPTIONS keys on instrument. On first line of Maintenance screen, instrument LCD should now read *Maintenance (Device Type)*, Current device type will be reflected in parentheses.

NOTE: After certain Instrument Configuration changes, configuration parameters (such as, Device Type Change Lockout) should be verified by exercising function that was changed, or by viewing parameter value on instrument. Appendix contains procedures for verifying parameter values and is referenced throughout this chapter.

Custom Instrument Configuration

When making changes to specific parameters of a device type, changes are only valid for selected device types. Changes must be repeated for each device type, as required.

Some parameter changes will affect entire instrument and are specifically noted. When making changes to parameters that will affect entire instrument, the instrument can be set in any device type.

Reset Faults (Selection 00)

RESET faults clears the fault from memory. It does not repair anything. If the condition that triggered the fault has not been addressed, the fault will re-occur.

When a channel is in SERVICE status, it may be made operational again by using *Reset Faults* command from Instrument Configuration Commands Menu. Command resets faults on all channels. The fault will re-occur if a hardware problem exists (See Technical Service Manual).

This command can be verified by turning instrument off and on again. Status of all channels should be operational.

CAUTION

Do not return instrument to clinical use after resetting faults without first referring to instrument's Technical Service Manual. Additional testing or servicing may be required for specific faults.

Clear Instrument Logs (Selection 01)

Event, Alarm, and Status Logs (which are stored in instrument memory) can be cleared using *Clear Log* command from Instrument Configuration Commands Menu.

After *Clear Log* command is issued, user has a choice of which log to clear:

Event Log
Alarm Log
Status Log

After *Clear Log* command is issued, press Esc key to return to Main Menu. To verify cleared log, select Logs Menu, then retrieve and display appropriate log from instrument.

Reset Rate, VR, and Time to Default Values (Selection 02)

Software errors and out-of-range values may cause a persistent Watchdog 30,x condition (parameter out of range). This condition may be corrected by issuing *Reset Rate, VR, and Time* command from Instrument Configuration Commands Menu.

Reset Rate, VR, and Time - Resets Rate, VR, and Time Remaining to default values.

This command can be verified by turning instrument off and on again. Rate, VR, and Time Remaining of all channels should be reset to default values.

NOTE: The Watchdog 30,x message appears when instrument is powered up and will be listed in Event Log. Refer to Technical Service Manual for more detailed watchdog information.

Set Instrument Serial Number (Selection 03)

Instrument displays Title page and Instrument Settings pages (see instrument DFU). This information is kept in the instrument memory, and it may be lost if power is disrupted or instrument is exposed to high levels of static electricity.

User can enter serial number into instrument using *Set Instrument Serial Number* command from Instrument Configuration Commands Menu. Serial number must be 3 - 9 digits long. Use serial number found on back label of instrument.

This number is used for identification in every log.

Always verify that correct serial number was entered by turning instrument off, then on, keeping ON/OFF key depressed to observe serial number on Title page.

> **NOTE:** If this command is executed, the instrument will return the value that was entered for user verification.

Set User Information Line (Selection 04)

Instrument is capable of displaying an ID line of up to 25 characters, including spaces, on Title page. Text for User Information line can be set using *Set User Information Line* command from Instrument Configuration Commands Menu.

Always verify that correct User Information line was entered by turning instrument off, then on, keeping ON/OFF key depressed and observing Title page.

> **NOTE:** If this command is executed, the instrument will return the value that was entered for user verification.

Special Note Message / Enable / Set Date (Selections 05, 06, 07)

A provision is made for a Special Note page on which you can enter up to five lines of text. This page appears when instrument is turned on and after Title page clears, provided *Special Note* date is same as or earlier than current date shown on Instrument Settings page.

Special Note page is enabled or disabled with *Enable/Disable Special Note* command from Instrument Configuration Commands Menu. Date to display Special Note page is entered by *Set Date To Display Special Note* command from Instrument Configuration Commands Menu. Each line of text (up to a maximum of five lines and 27 characters including spaces) is entered separately after appropriate line number by using *Set Special Note Messages* command from Instrument Configuration.

> **NOTE:** Digits will not be accepted as first character of a line on Special Note page. To have a digit as first character, precede it with a space.

Commands menu
The Following input enters a Special Note Message:

Message Line 1: *This instrument should be*
Message Line 2: *Returned to Biomed for*
Message Line 3: *Annual maintenance*
Message Line 4: *(blank)*
Message Line 5: *(blank)*

Special Note Message reads:

> This instrument should be
> Returned to Biomed for
> Annual maintenance.

After a special note is entered, enabled, and display date is set correctly, the message can be verified by exiting Maintenance Mode by turning instrument off, then on. After Title page clears, Special Note page appears. Press CLEAR softkey to bypass message.

> **NOTE:** If this command is executed, the instrument will return the value that was entered for user verification.

Clear Battery Installation Dates and Clear Battery Log (Selection 08, 09)

Instrument will display main and backup installation dates on Battery History Log, accessible by using BATLOG softkey. Installation dates can be cleared using the following commands.

Clear Main Battery Date - Clears Main Battery Installation Date and Battery Log contents. This command will reset all fields in the log, other than the backup battery date, to 0 or ----.

> **NOTE:** This should always be executed anytime the backup battery has been disconnected.

Clear Backup Battery Date - Clears only Backup Battery Installation Date.

This command can be verified by using Verification Procedure D located in appendix section..

Reset Device Specific Parameters (Selection 10)

This feature is used to reset device specific parameters such as Air-in-line thresholds, Patient-side-occlusion thresholds, Clear Air parameters, and Rate/Volume boundaries back to manufacturer settings.

This command can be verified by using Verification Procedure B located in appendix section.

Enable/Disable ClrAir Softkey (Selection 11)

ClrAir softkey is activated after accessing air-related alarm information for affected channel. This feature can be enabled/disabled for selected Device Type from Instrument Configuration Commands Menu.

This command can be verified by using Verification Procedure B located in appendix section.

Change Rate Breakpoint for ClrAir Softkey (Selection 12)

ClrAir softkey is normally activated for current device type after a predetermined rate breakpoint. If a different rate breakpoint is desired, it can be changed by using *Change Rate Breakpoint for ClrAir* command from Instrument Configuration Commands Menu.

This command can be verified by using Verification Procedure A located in appendix section.

Lock/Unlock Dose Rate Calculate (Selection 13)

This feature allows user to lock out Dose Rate Calculator function of instrument by using Lock/Unlock Dose Rate Calculator command from Instrument Configuration Commands menu. When command is set to Locked Out, Dose Rate Calculator feature is not accessible. When command is set to Unlocked, Dose Rate Calculator feature is available.

NOTE: This feature is not device type specific.

This command can be verified by using Verification Procedure C located in appendix section.

Set Keep Vein Open Rate (Selection 14)

After an infusion is complete on a channel (VR=0), instrument will generate an Infusion Complete Advisory. If a channel is infusing at a rate higher than Keep Vein Open (KVO) rate, it will automatically change to KVO rate. KVO rate can be customized for different device types. For range of available KVO rates see table below.

Device Type	KVO Rates	Increments
General Purpose Operating Room Controller Pressure	1.0 to 20 ml/h	1.0 ml/h
General Purpose II Operating Room II	1.0 to 20 ml/h	1.0 ml/h
Neonatal	0.1 to 5 ml/h	0.1 ml/h

Set Keep Vein Open Rate (Selection 14)
(Continued)

Changing KVO rate is done by selecting *Set KVO Rate for Device Type* from Instrument Configuration Commands Menu. After user selects desired device type, allowable range will be displayed for user to select their chosen value.

This command can be verified by using Verification Procedure A located in appendix section.

NOTE: If this command is executed, the instrument will return the value that was entered for user verification.

Set Maximum Primary Rate (Selection 15)

For Maximum rate range allowable by user when instrument is operating in Primary regimen refer to the table below. Also see instrument DFU.

Device Type	Maximum Rates
General Purpose Operating Room	1-999 ml/h
General Purpose II Operating Room II	1-999 ml/h
Controller Pressure	1-299 ml/h
Neonatal	0.1-99.9 ml/h

Changing maximum primary rate is done by selecting *Set Maximum Rate for Device Type* from Instrument Configuration Commands Menu. After user selects desired device type, allowable range will be displayed when selecting new value.

This command can be verified by using Verification Procedure A located in appendix section.

NOTE: If this command is executed, the instrument will return the value that was entered for user verification.

Set Maximum Primary Volume Remaining (Selection 16)

Maximum VR range allowable by user when instrument is operating in Primary regimen of Dual Rate mode is 1-9999 ml for all device types. (see instrument DFU).

To change maximum primary volume remaining select *Set Maximum VR for Device Type* from Instrument Configuration Commands Menu. After user selects desired device type, allowable range will be displayed for user to select a new value.

This command can be verified by using Verification Procedure A located in appendix section.

> **NOTE:** If this command is executed, the instrument will return the value that was entered for user verification.

Set Maximum Secondary Rate (Selection 17)

For maximum rate range allowable by user for Secondary regimen for a device see table below. Also refer to instrument DFU.

Device Type	Maximum Rates
General Purpose Operating Room	1-999 ml/h
General Purpose II Operating Room II	1-999 ml/h
Controller Pressure	1-299 ml/h
Neonatal	0.1-99.9 ml/h

To change maximum secondary rate select *Set Max Secondary Rate for Device* from Instrument Configuration Commands Menu. After user selects desired device type, allowable range will be displayed for user to select a new value.

This command can be verified by using Verification Procedure A located in appendix

> **NOTE:** If this command is executed, the instrument will return the value that was entered for user verification.

Set Maximum Secondary Volume Remaining (Selection 18)

Maximum Secondary VR range allowable by user in Dual Rate mode is 1-9999 ml for all device types. Also refer to instrument DFU.

To change maximum secondary VR select *Set Max Secondary VR for Device* from Instrument Configuration Commands Menu. After user selects desired device type, allowable range will be displayed for user to select a new value.

This command can be verified by using Verification Procedure A located in appendix.

> **NOTE:** If this command is executed, the instrument will return the value that was entered for user verification.

Enable/Disable Audio Volume Ramping (Selection 19)

Once activated, alarm volume on instrument automatically begins increasing to loudest level after 1 minute if alarm is not addressed. This feature can be enabled/disabled using *Enable/Disable Audio Ramping* command from Instrument Configuration Commands Menu.

> **NOTE:** This feature is not device type specific, and it changes alarm ramping for all device types.

This command can be verified by using Verification Procedure B located in appendix.

Set OFF Delay (Selection 20)

Turning off instrument normally requires pressing OFF key for 1 second. Using FMS, this time period can be changed to 3, 5, or 10 seconds by using *Set Instrument Off Delay* command from Instrument Configuration Commands Menu.

> **NOTE:** This feature is not device type specific.

This command can be verified by using Verification Procedure B located in appendix.

> **NOTE:** If this command is executed, the instrument will return the value that was entered for user verification.

Set Main Battery Installation Date (Selection 21)

Date main NiCd battery pack was last replaced can be entered into memory, using *Set Main Battery Install Date* command from Instrument Configuration Commands Menu.

> **NOTE:** This feature is not device type specific.

This command can be verified by using Verification Procedure D located in appendix.

> **NOTE:** If this command is executed, the instrument will return the value that was entered for user verification.

Set Memory-Backup Battery Installation Date (Selection 22)

Date internal memory-backup lithium battery was last replaced can be entered into memory by using *Set Backup Battery Install Date* command from Instrument Configuration Commands Menu.

> **NOTE:** This feature is not device type specific.

This command can be verified by using Verification Procedure D located in appendix.

> **NOTE:** If this command is executed, the instrument will return the value that was entered for user verification.

Set Fractional Scrolling Breakpoint (General Purpose II and Operation Room II only) (Selection 23)

Breakpoint at which Rate and VR change from 0.1 to 1.0 increments can be set using *Set Fractional Scrolling Breakpoint* command from Instrument Configuration Commands Menu.

This command is verified by actually scrolling rate and VR on a selected channel and observing that as value scrolls below breakpoint, it does so in 0.1 increments. When breakpoint is reached, value then scrolls in increments of 1.0.

> **NOTE:** If this command is executed, the instrument will return the value that was entered for user verification.

Lock/Unlock Device Type Change (Selection 24)

Current device type can be locked so that instrument users will not be able to change device type once it leaves the Biomedical Engineering Department. This is accomplished by using *Lock/Unlock Device Type Change* command from Instrument Configuration Commands Menu.

Setting command to Locked Out will lock device type in its current configuration. Setting command to Unlocked will allow device type to be changed.

This command can be verified by exiting Maintenance Mode by turning off instrument, then on. Press MORE OPTIONS key until DEVICE softkey appears. Press DEVICE softkey to verify that Device Type Change command is in effect.

Lock/Unlock IVPB (Selection 25)

Instrument channels are capable of operating in Primary or Secondary/IVPB mode. Instrument can be configured to prevent changing channel modes once they have been set for all three channels. This is accomplished by using *Lock/Unlock IVPB* command from Instrument Configuration Commands Menu.

Setting command to Locked Out will lock out Secondary/IVPB mode for all channels. Setting command to Unlocked will allow Secondary/IVPB mode on all channels.

> **NOTE:** This change will affect all device types.

This command can be verified by using Verification Procedure B located in appendix.

Enable/Disable ALL Settings for VR (Selection 26)

As a general rule, when specifying Volume Remaining (VR) on instrument, a value is entered showing number of milliliters of solution to be delivered. A feature that allows VR to be set to *ALL* is available only for Operating Room and Operating Room II Device Types.

When VR is set to *ALL*, instrument will continue infusing until solution container is empty and air is detected by Air-in-Line detector of instrument channel. ALL mode availability can be enabled for Operating Room and Operating Room II Device Types by using *Enable/Disable ALL Setting for VR* command from Instrument Configuration Commands Menu.

Setting *ALL* mode availability to Disable (meaning No) prevents setting VR to *ALL*. Setting *ALL* mode availability to Enable (meaning Yes) enables *ALL* mode in VR.

> **NOTE:** This command alters ALL mode availability for Operating Room and Operating Room II Device Types only.

This command can be verified by using Verification Procedure A located in appendix.

CAUTION

Hospital policies and procedures should be consulted when determining appropriate Air-in-line thresholds. As a general guideline, set lowest thresholds appropriate when patient susceptibility to infused air is an important clinical consideration.

Set Air-in-Line Alarm Sensitivity (Selection 27)

Air-in-line parameters can be customized according to the standards of an institution. Air-in-line algorithm generates an alarm when it detects a certain volume of air (threshold) in a specific volume of fluid (window).

Alarm threshold and level can be altered using *Set Air-in-line Alarm Sensitivity* command from Instrument Configuration Commands Menu. Thresholds are defined in “Air-in-line Configuration” figure shown below. Entry of any Air-in-line threshold values other than those shown in “Air-in-line Configuration” figure are not allowed.

This command can be verified by using Verification Procedure A located in appendix section.

NOTE: If this command is executed, the instrument will return the value that was entered for user verification.

AIR-IN-LINE CONFIGURATION

Window	Threshold	Available ?
1 ml	10 µl *	All device types
1 ml	25 µl *	All device types
1 ml@@@	50 µl@@@	All device types
1 ml	75 µl	All device types
1 ml	100 µl	All except Neonatal
1 ml	150 µl	All except Neonatal
1 ml	250 µl	Not available
1 ml	500 µl	Not available
2 ml	10 µl *	All device types
2 ml	25 µl *	All device types
2 ml	50 µl	All device types
2 ml	75 µl	All device types
2 ml	100 µl	All device types

Set Air-in-Line Alarm Sensitivity (Selection 27) (Continued)

AIR-IN-LINE CONFIGURATION (continued)

Window	Threshold	Available ?
2 ml	150 µl *	All except Neonatal
2 ml	250 µl *	All except Neonatal
2 ml	500 µl	Not available
3 ml	10 µl	All device types
3 ml	25 µl	All device types
3 ml	50 µl	All device types
3 ml	75 µl	All device types
3 ml	100 µl	All device types
3 ml	150 µl *	All except Neonatal
3 ml	250 µl *	All except Neonatal
3 ml@@	500 µl@@	All except Neonatal

*10 and 25-microliter thresholds are approximate due to inherent difficulties in creating and measuring air bubbles of such small size during testing. On the configuration display 25 will be indicated by <50, 10 will be indicated by <<50.

@@ Factory setting

@@@ Neonatal default setting

Set Incremental Pressure (Selection 28)

Incremental pressure above baseline value, at which a Patient-side Occlusion alarm is generated, can be customized using *Set Increment Pressure* command from Instrument Configuration Commands Menu. Range for incremental pressure is from 1 to 15 psi (in 1-psi increments) for General Purpose, General Purpose II, Operating Room, Operating Room II, and Neonatal Device Types. Incremental pressure is not applicable when instrument is operating in Controller Pressure Device Type.

This command can be verified by using Verification Procedure A located in appendix.

NOTE: If this command is executed, the instrument will return the value that was entered for user verification.

Set Maximum Pressure (Selection 29)

Maximum pressure at which a patient-side occlusion alarm is generated can be set using *Set Maximum Pressure* command from Instrument Configuration Commands Menu. Range for maximum pressure is 4 to 15 psi (in 1-psi increments) for General Purpose, General Purpose II, Operating Room, Operating Room II, and Neonatal Device Types, and 1 to 6 ft H_20 (in 1-ft H_20 increments) in Controller Pressure Device Type.

The pressure at which a Patient-side Occlusion alarm is generated will be either incremental pressure over baseline, or maximum pressure setting, whichever is lower.

This command can be verified by using Verification Procedure A located in appendix section.

> **NOTE:** If this command is executed, the instrument will return the value that was entered for user verification.

Lock/Unlock Dose Parameters (Selection 30)

This feature allows user to access and change drug concentration parameters and dose rate parameters for all drugs in Dose Rate Calculator. This is accomplished by using *Lock/Unlock Dose Parameters* command from Instrument Configuration Commands Menu.

Setting command to Locked Out will not allow user to change drug concentration units and dose rate units for any drugs (except DRUG?). Setting command to Unlocked will allow drug concentration units and dose rate units for all drugs to be changed.

This command can be verified by using Verification Procedure B located in appendix.

Reset Configuration Data (Selection 31)

This feature allows instrument to be reconfigured with factory settings. This feature includes configuration command *Reset Rate, Volume Remaining, and Time to Default Values*. User can access this feature by using *Reset Configuration Data* command from Instrument Configuration Commands Menu.

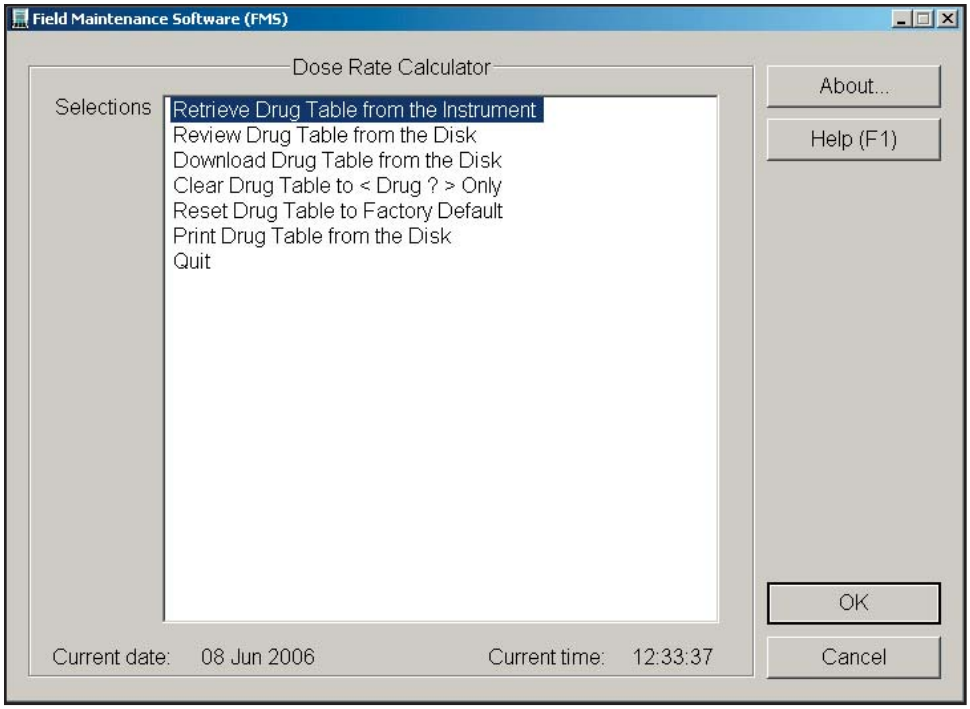
This command can be verified by using Verification Procedure B located in appendix.

Dose Rate Calculator

This feature allows user to configure, review, and print Dose Rate Calculator Drug Table file. User selects desired option by using keyboard arrows or by typing first character, then pressing ENTER key. See “Dose Rate Calculator Menu” figure below. The following options are also included:

- Retrieve drug table from instrument.
- Review a drug table from disk in computer.
- Download a drug table from disk in computer.
- Clear drug table to (DRUG?) only.
- Reset drug table in instrument to factory default.
- Print drug table from disk in computer.
- Quit Dose Rate Calculator (and return to Instrument Programming Menu).

Dose Rate Calculator Menu



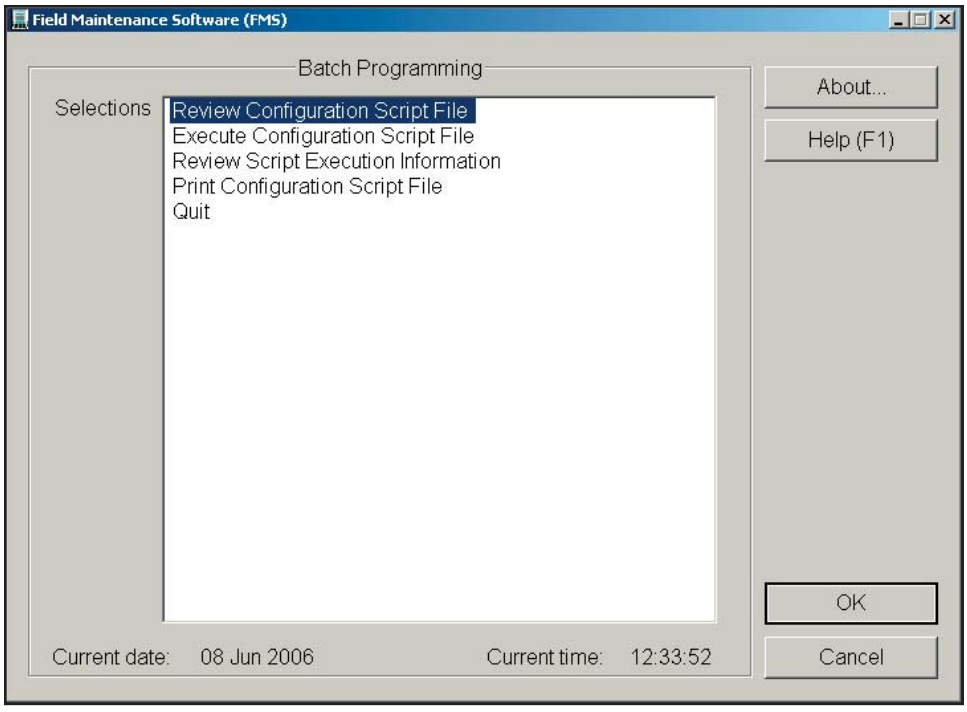
Drug table has a convention extension, ***.drc***. drug table will contain information on Drug Number, Drug Name, Drug Dosage, Diluent Volume, Dose Regimen, Weight, Time, Fast Next, and Fast Previous.

Batch Programming

This feature allows user to manipulate instrument configuration script files, and execute a file to an instrument. See “Batch Programming Menu” figure shown below. The following options are also included:

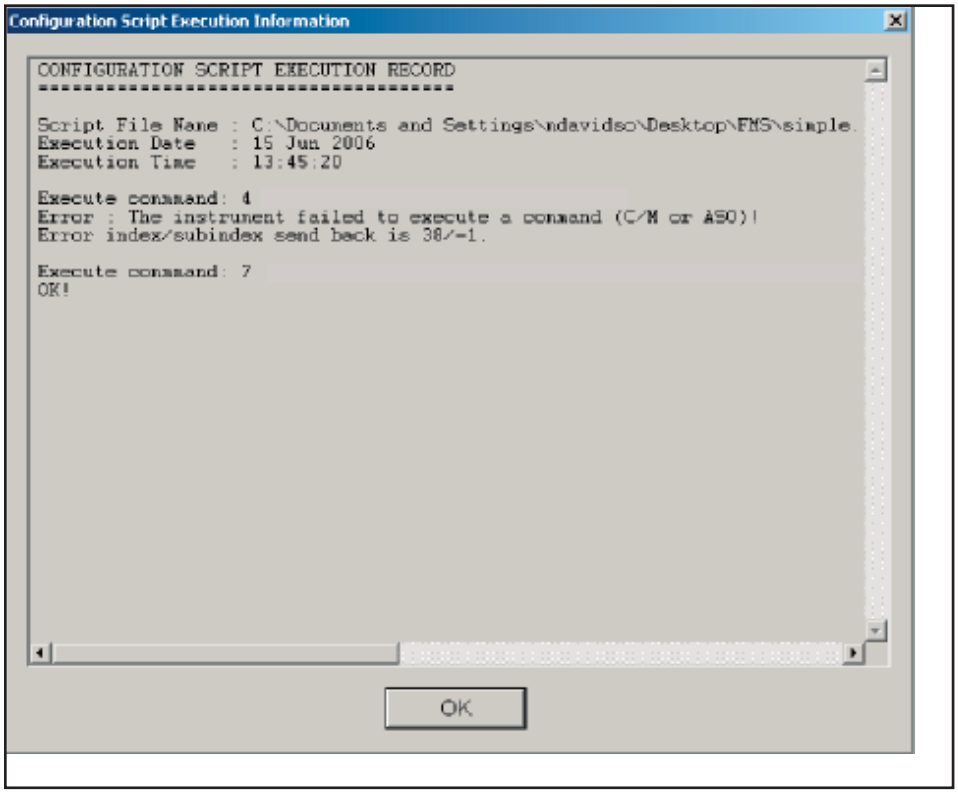
- Review a script file from disk in computer. Script files have convention extension .ics.
- Execute one script file to an instrument (such as, change instrument to settings specified in script file).
- Review result of an execution of a script file to an instrument. Script files use script file name plus convention extension ***.inf.*** See “Sample and Explanation of a Batch Execution Script File” figure.
- Print a script file from disk in computer.
- Quit Batch Programming (and return to Instrument Programming Menu).

Batch Programming Menu



Instrument Programming (Continued)

Sample and Explanation of a Batch Execution Script File



Calibration

Differences among instrument components (such as, transducers, mechanical components, circuit gains and offsets) necessitate calibration of certain systems. These systems detect cassette installation, latch closure, patient-side occlusions, and fluid-side occlusions.

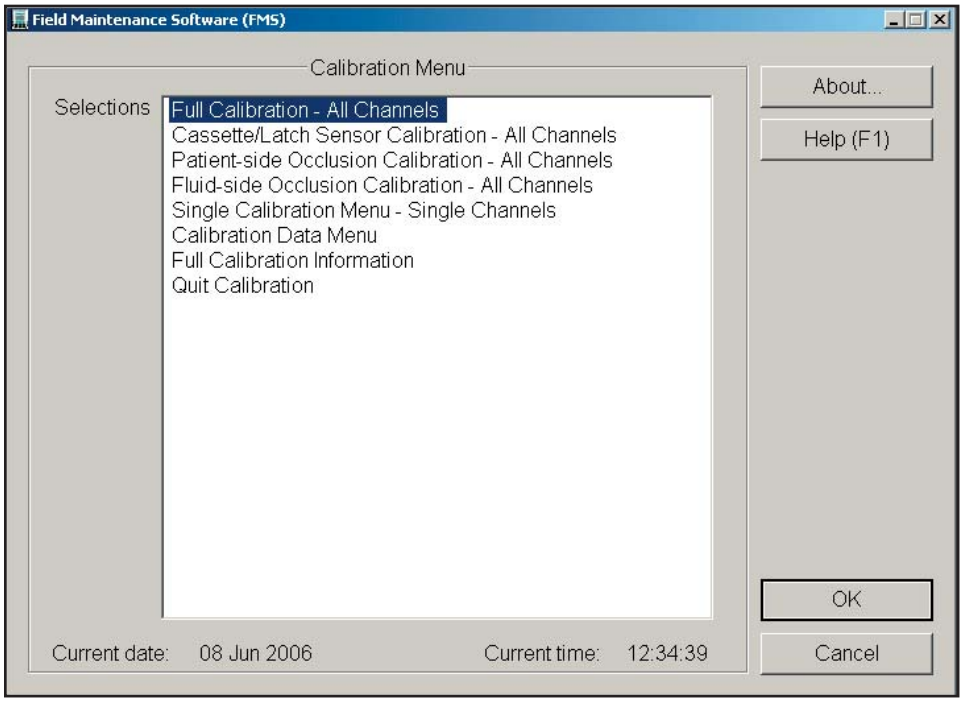
Software functions are used to perform instrument calibrations. Calibration is required after replacing certain components as a part of preventive maintenance, or if memory contents are corrupted. Refer to Technical Service Manual for help in troubleshooting calibration failures.

Every calibration step will display a series of numbers and a pass or fail message. These numbers are A/D results from a calibration step. In the event of a failure the numerical results aid in diagnosis.

Calibration Options

There are six basic options from which to choose when calibrating instrument. See “Calibration Menu” figure shown below.

Calibration Menu



Full Calibration - All channels

This guides user through calibration procedures for all sensor systems on all channels. This is used most often for annual maintenance. It is suggested as a best practice to run a full calibration whenever calibration is done to calibrate an entire system.

Single Sensor Calibration - Options:

Cassette/Latch Sensor Calibration - All channels
Patient-side Occlusion Calibration - All channels
Fluid-side Occlusion Calibration - All channels

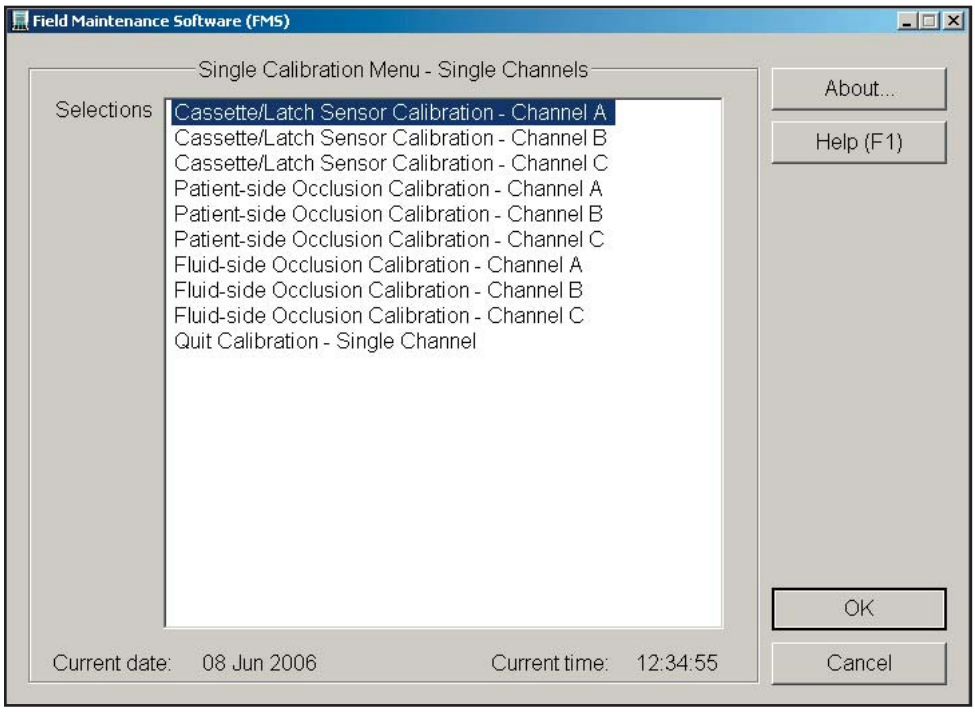
Calibration Options (Continued)

These options allow user to simultaneously calibrate individual sensor systems for all channels. This is used most often when troubleshooting.

Single Calibration Menu - Single Channels

This guides user through steps necessary to calibrate an individual channel (such as, cassette sensors for Channel A), as shown below. A single calibration is useful for troubleshooting a single aspect of an individual channel.

Single Calibration Menu - Single Channels



Calibration (Continued)

Calibration Data Menu

This menu provides user ability to retrieve calibration data from instrument and store it to a file on disk.

Calibration file naming convention is 3 - 9 digit serial number of instrument plus:

!C for current instrument calibration log file (*12345678.9!C*);
#C for backup instrument calibration log file (*12345678.9#C*).

This menu also provides user with ability to review data files from disk in computer and to print data.

Full Calibration Information

This menu provides user with ability to review full calibration conversation files from disk in computer.

Calibration file naming convention is 3 - 9 digit serial number of instrument plus:

!F for current full calibration information file (*12345678.9!F*);
#F for backup full calibration information file (*12345678.9#F*).

This menu also provides user ability to print full calibration conversation files from disk in computer.

Quit Calibration returns user to Main Menu.

Calibration Prerequisites

- *Cassette/Latch Sensor Calibration* with no cassettes installed must be completed before Cassette/Latch Sensor Calibration with cassettes installed.
- 0 psi Calibration must be performed before 12 psi Calibration can be performed.
- *Cassette/Latch Sensor Calibration* must be performed before Fluid-side Occlusion Calibration can be performed.
- *Fluid-side Occlusion Calibration* with no load must be performed before *Fluid-side Occlusion Calibration* with a load can be performed.

Starting Calibration

Select *Calibration Menu* from FMS Main Menu. Select desired calibration option. For FMS to access calibration functions described in this section, instrument must be placed in *Maintenance* Mode.

To place instrument in Maintenance Mode, turn on instrument by simultaneously pressing ON/OFF and MORE OPTIONS keys. Instrument LCD should now read *Maintenance*, followed by current device type.

> **NOTE:** Always perform calibration procedures with instrument connected to AC power. Instrument battery alarms are not active in Maintenance Mode.

> **NOTE:** Ensure all channels have required equipment, as described in following procedures. Otherwise, calibration parameters will be out of range.

Whether calibration is full or single channel, set up process of each step is the same and the following details in full calibration for brevity.

If a failure is determined, follow prompts to repeat calibration procedures.

Every calibration step will display a series of numbers and a pass or fail message. These numbers are A/D results from a calibration step. In the event of a failure the numerical results aid in diagnosis.

Always perform a functional test after calibration is completed to ensure proper operation of equipment.

Full Calibration

Full calibration performs calibration with following the criteria:

- No cassette installed and pressure zero calibration
- Cassette installed and 12-psi pressurized cassette calibration
- 12-psi pressure verification
- 6-psi pressure verification
- 0-psi pressure verification
- Fluid-side Occlusion calibration with no load
- Fluid-side Occlusion calibration with load

Cassette/Latch Sensor/OPSI Calibration

To begin Cassette/Latch Sensor Calibration, you will need one to three administration sets that have been modified for Cassette/Latch Sensor Calibration by cutting inlet tubing from cassette, depending on whether single-channel or all-channel calibration is to be performed.

During full calibration a cassette/latch sensor and patient side occlusion calibration, which are both 2 step processes, are done at the same time. During the single calibration or the single sensor calibration there will be separate 2 step calibrations.

> **NOTE:** During Full Calibration, Cassette/Latch Sensor Calibration requires installation of cassettes pressurized at 12 psi during step 2.

Cassette/Latch sensor calibration is performed as follows:

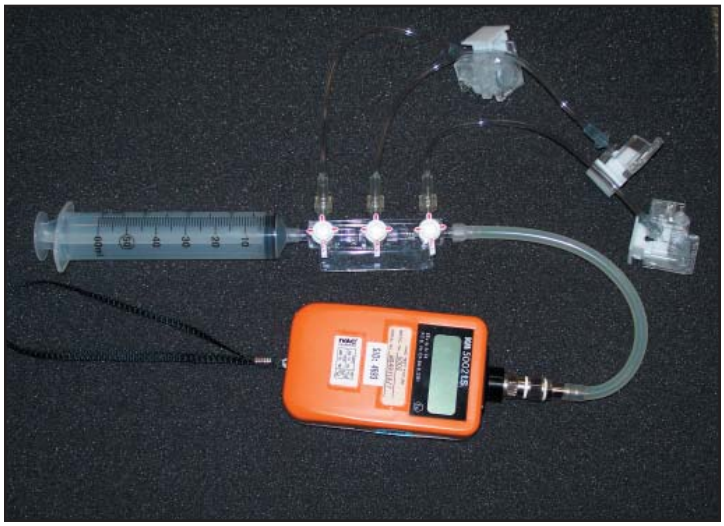
Step 1. Calibrate with no cassette installed.

Remove cassettes from all three channels. Ensure that optomodule sensors are clean and free of debris. Verify pump latch is open. When prompted by FMS, press Enter key. INSTRUMENT RESPONSE block will indicate whether a channel passed or failed calibration. If a channel fails calibration, make sure directions given by FMS have been followed. If a channel consistently fails, refer to Technical Service Manual for troubleshooting procedures.

Step 2. Calibrate with a cassette installed.

When prompted by FMS, install cassettes in appropriate channels and press Enter key. INSTRUMENT RESPONSE block will indicate which channels passed or failed calibration. If a channel fails calibration, make sure directions given in FMS have been followed. If a channel consistently fails, refer to Technical Service Manual for troubleshooting procedures.

Example of a Patient-side Occlusion Set



Patient-side Occlusion Calibration

Equipment required for this calibration is as follows:

- A regulated air pressure source of up to 15.00 ± 0.05 psig.
- A pressure gauge (preferably digital) that will measure 0 to 20.0 psig, ± 0.5% full scale with a resolution of 0.1 psig.
- 1 to 3 administration sets that have been modified for pressure calibration by cutting inlet tubing flush with air trap. Depending on whether single-channel or all-channel calibration is to be performed. Do not remove piston sleeve, as air will leak from set.
- Three three-way stopcocks.

An example is shown above.

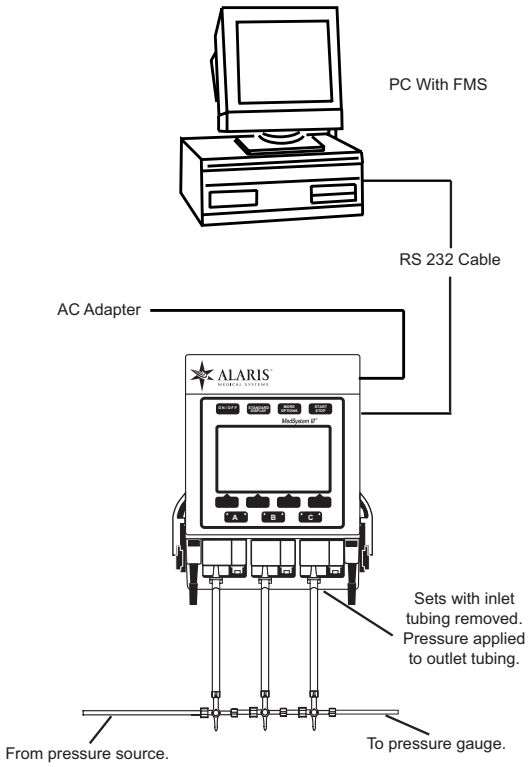
NOTE: Digital pressure gauges that meet or exceed these requirements are available from Cole-Parmer Instrument Company; 7425 North Oak Park Avenue; Chicago, IL 60648 or other laboratory supply companies.

NOTE: A 60-ml luer-lock syringe can be used as a pressure source. Adjust plunger so that gauge reads required pressure. Then close stopcock to syringe so that pressure is held constant. Ensure that there are no leaks in system that could cause pressure to drop. A regulated source from a compressor or pressurized gas tank can also be used.

NOTE: A manifold with three-way stopcocks is available from Cole-Parmer catalog # U-06464-82.

Patient-side Occlusion Calibration (Continued)

Administration Set Calibration Configuration



Configure apparatus as shown in figure “Administration Set Calibration Configuration”.

Patient-side Occlusion Calibration is performed as follows.

Step 1. Pressure Zero Calibration

> **NOTE:** During Full Calibration pressure zero was done during the Cassette/Latch sensor Øpsi calibration.

Ensure that all cassettes are removed and all latches are open. Press Enter key to continue test. INSTRUMENT RESPONSE block will indicate which channels passed or failed. If a channel fails calibration, make sure that directions given by FMS have been followed. If a channel consistently fails, refer to Technical Service Manual for troubleshooting procedures.

Patient-side Occlusion Calibration (Continued)

Step 2. 12-psi Pressurized Cassette Calibration

Ensure that pressurized cassettes are installed and that pressure is set to 12 psi +1% (620.4 mmHg). Press Enter key to continue test. INSTRUMENT RESPONSE block will indicate which channels passed or failed. If a channel fails calibration, make sure that directions given by FMS have been followed. If a channel consistently fails, refer to Technical Service Manual for troubleshooting procedures.

Step 3. 12-psi Pressure Verification

Repeat **Step 2.**

Step 4. 6-psi Pressure Verification

Ensure that pressurized cassettes are installed and pressure is set to 6 psi +1% (310.2 mmHg). Press Enter key to continue test. INSTRUMENT RESPONSE block will indicate which channels passed or failed. If a channel fails calibration, make sure that directions given by FMS have been followed. If a channel consistently fails, refer to Technical Service Manual for troubleshooting procedures.

Step 5. 0-psi Pressure Verification

Ensure that pressurized cassettes are installed and that pressure is set to 0 psi. Press Enter key to continue test. INSTRUMENT RESPONSE block will indicate which channels passed or failed. If a channel fails calibration, make sure that directions given by FMS have been followed. If a channel consistently fails, refer to Technical Service Manual for troubleshooting procedures.

Fluid-side Occlusion Calibration

Equipment required for Fluid-side Occlusion calibration is as follows.

- Fluid-side Occlusion calibration fixture.
- One to three cassettes depending on whether single-channel or all-channel calibration is to be performed which have been modified for Fluid-side Occlusion calibration.

Cassette modification consists of removal of piston sleeves from piston area. DO NOT REMOVE PISTON. Remove elastomeric valve area in cassette, using a pointed X-acto knife. Administration sets can be made easier to handle by shortening inlet and outlet tubing. A set of 3 pre modified cassettes can be ordered as part #148169-100. A set of them come with calibrations device part #2861461. See figure 1 and figure 2.

Fluid-side Occlusion Calibration (Continued)

Figure 1

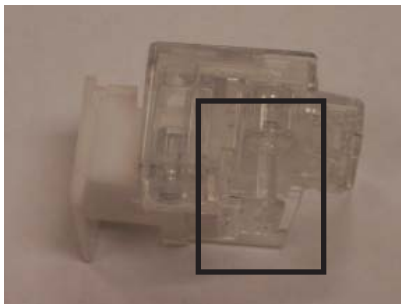
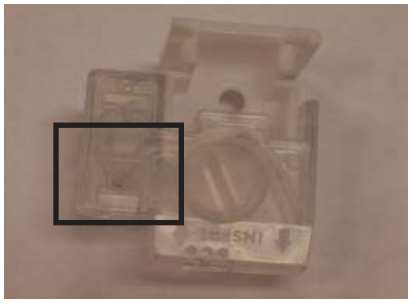


Figure 2



> **NOTE:** When performing a Fluid-side Occlusion calibration procedure, be sure to use cassettes that have been modified for Fluid-side Occlusion. Use of cassettes with piston sleeves during Fluid-side Occlusion calibration can result in erratic performance.

This calibration procedure is performed as follows.

Step 1. Fluid-side Occlusion Calibration with No Load

Insert Fluid-side Occlusion calibration cassettes. Place instrument into a 90° upright position. Press Enter key to continue test. INSTRUMENT RESPONSE block will indicate which channels passed or failed. Motors will run for approximately two minutes. If a channel fails calibration, make sure that directions given in FMS have been followed. If a channel consistently fails, refer to Technical Service Manual for troubleshooting procedures.

Step 2. Fluid-side Occlusion Calibration with Load

> **NOTE:** Before performing Step 2, look through three slots on face of Fluid-side Occlusion calibration fixture and verify that weights in fixture move freely. If fixture has been dropped, replacement may be necessary. See Service Bulletin 497 for the procedure to check for proper function.

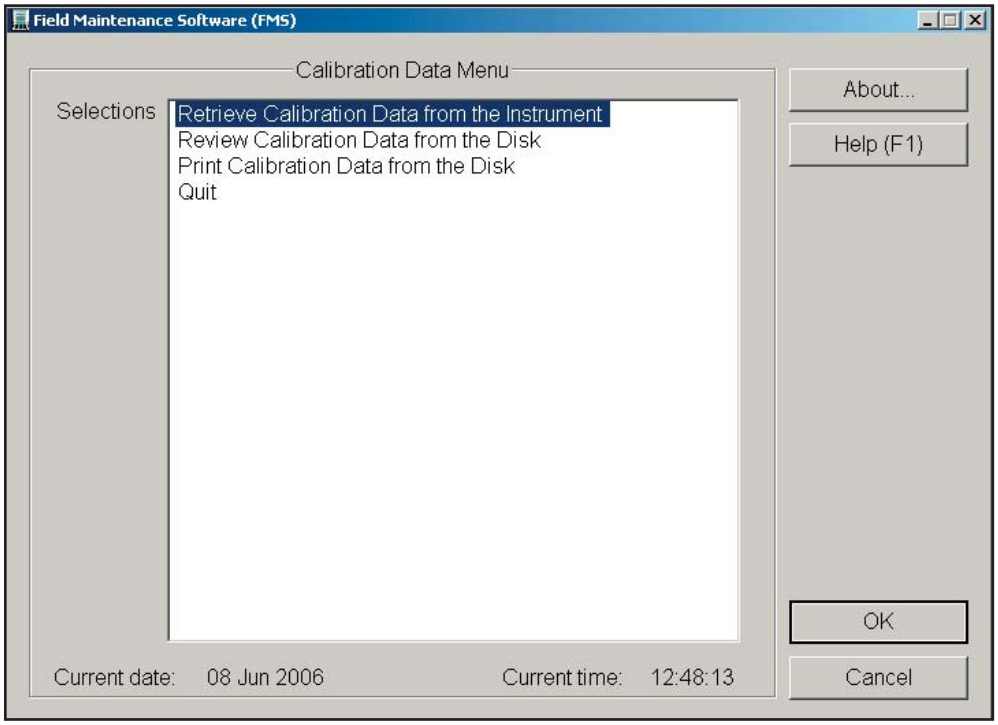
Turn instrument upside down and position it vertically. Remove lower housing. Place Fluid-side Occlusion calibration fixture on instrument in place of lower housing. Ensure that weight shafts are aligned with pump latches. Press Enter key to continue test. Motors will run for approximately 2 minutes. If a channel fails calibration, make sure that directions given by FMS have been followed. If a channel consistantly fails, refer to Technical Service Manual for troubleshooting procedures.

Calibration Data Menu

Calibration Data Menu option provides commands for retrieving from instrument, storing, displaying, or printing of calibration data. Calibration data displays operator's comments, instrument serial number, software version, date and time, and retrieved calibration data. Data will reflect whether all sensors for each channel completed required calibration. See figure "Calibration Data Menu".

To access these commands, instrument must be placed in Maintenance Mode by simultaneously pressing ON/OFF and MORE OPTIONS keys. Next, *Calibration Menu* is selected from Main Menu. Then, *Calibration Data Menu* is selected from Calibration Menu.

Calibration Data Menu



Calibration Data Menu (Continued)

Following are Calibration Data Menu options:

1. Retrieve Calibration Data from Instrument

If retrieved calibration data is stored on disk, the following information is requested.

Operator Comment (optional) - This information can be the name of person storing calibration data from instrument or any other information, up to a maximum of 20 characters, including spaces. Information will be stored on disk along with calibration data and will also appear on printouts. Retrieved file names are created using serial number, as shown in following example.

S/N 123456789 creates file: *12345678.9!C*

2 trailing characters (!C) are used by FMS to identify files as retrieved calibration data. If a retrieved calibration data file for a particular instrument already exists, FMS will prompt user to make a decision on whether to rename existing file and store it as a new file, append new data to existing file, or delete existing file and create a new one.

If a file is renamed, 2 trailing filename characters to identify file will be ***#C.***

2. Review Calibration Data from Disk

This is used to display calibration data that has been stored in a selected computer file. See “Retrieved Calibration Data Report” figure.

3. Print Calibration Data from Disk

This is used to print calibration data that has been stored in a selected computer file.

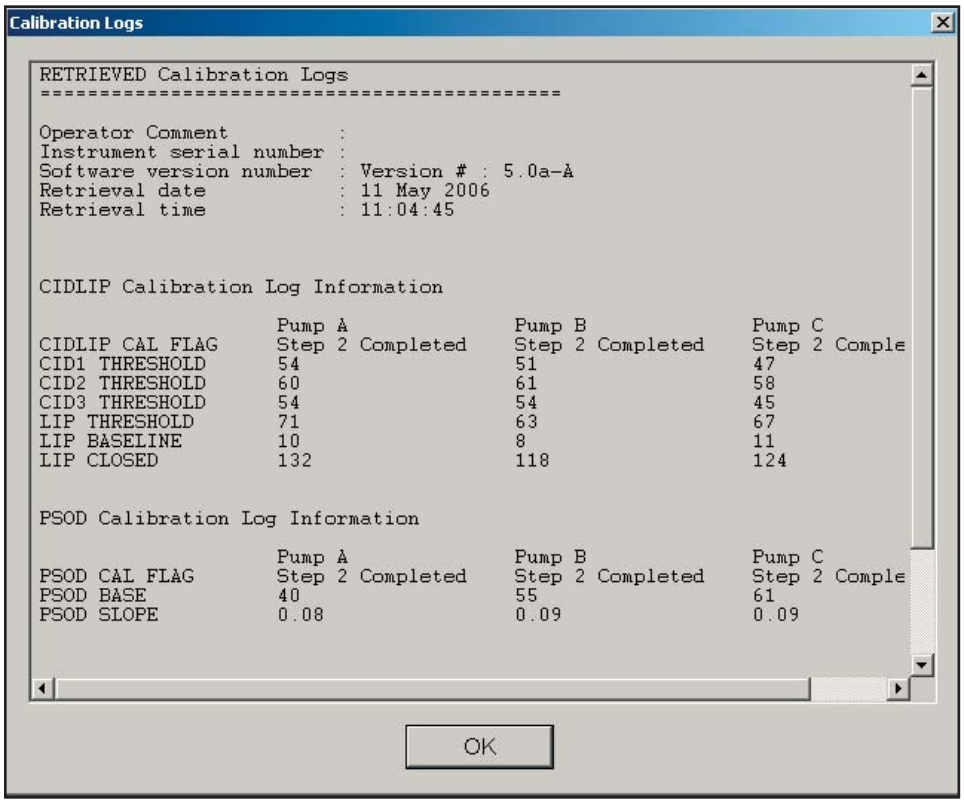
4. Quit

This is used to exit Calibration Data Menu and return to Calibration Menu.

NOTE: Calibration files for more than one instrument may exist on current disk. When displaying or printing data from a file, user must enter desired instrument serial number or press space bar to provide a directory of Calibration Data files that are available on current disk. Up or down arrow keys can then be used to highlight desired serial number. Press Enter key to retrieve desired Calibration Data file name. Press Enter key to retrieve file for displaying or printing.

Calibration Data Menu (Continued)

Retrieved Calibration Data Report



Full Calibration Information Menu

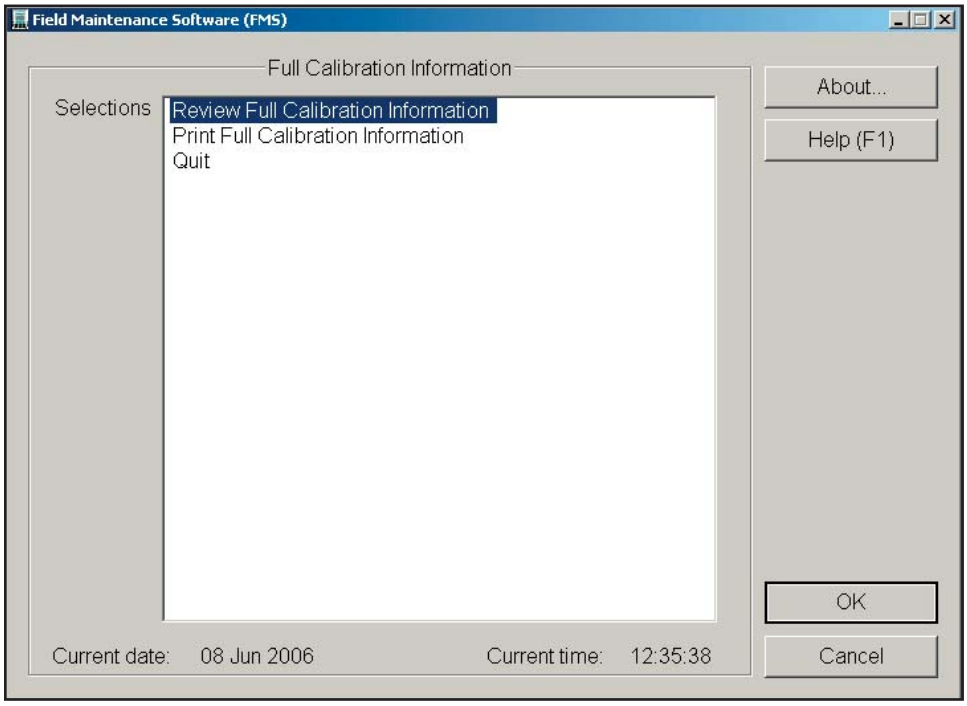
Full Calibration Information Menu allows user to review (display) and print calibration information obtained during a Full Calibration and stored to a file. See figure “Full Calibration Information Menu”.

Full Calibration Information Menu option provides user the following commands:

- Review Full Calibration Information
- Print Full Calibration Information

Full Calibration Information Menu (Continued)

Full Calibration Information Menu.



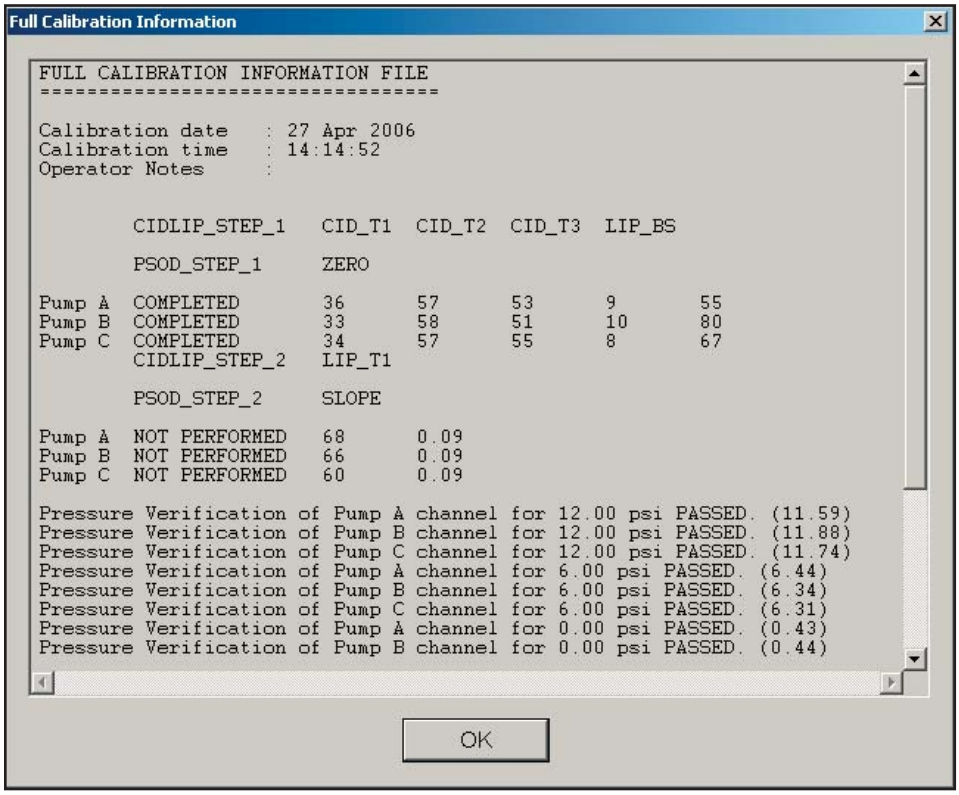
Full Calibration file names are created using serial number, plus extension ***!F*** as shown in following example. See “Full Calibration Report” figure.

S/N 123456789 creates file: *12345678.9!F*

If a Full Calibration data file for a particular instrument already exists, FMS will prompt user to make a decision on whether to rename existing file and store it as a new file, append new data to existing file, or delete existing file and create a new one.

Filename for a backup Full Calibration file includes serial number of instrument plus extension ***#F***. If a file is renamed, 2 trailing characters to identify file will be ***#F***.

Full Calibration Report



Exiting Calibration Menu

To exit Calibration Menu and return to Main Menu, select *Quit Calibration Menu* command and press Enter key.

Logs Menu

Instrument keeps a record of occurrences (such as, Watchdog alarms, changes in device type, and faults) in a log. Logs Menu allows user to access this information, and to save it in a file to any specified drive and directory path.

Logs Menu includes following options:

- Event Log
- Alarm Log
- Status Log
- All Logs
- Quit Logs Menu

In each option selected (except Quit Logs Menu), option menu allows user to specify a drive and directory path for each of following menu choices:

Retrieve Log from instrument.

> **NOTE:** If log already exists on disk, FMS provides an option to rename, delete, or append old log file. Log will be retrieved from instrument and displayed on monitor screen. When retrieval is complete, user can scroll throughout log.

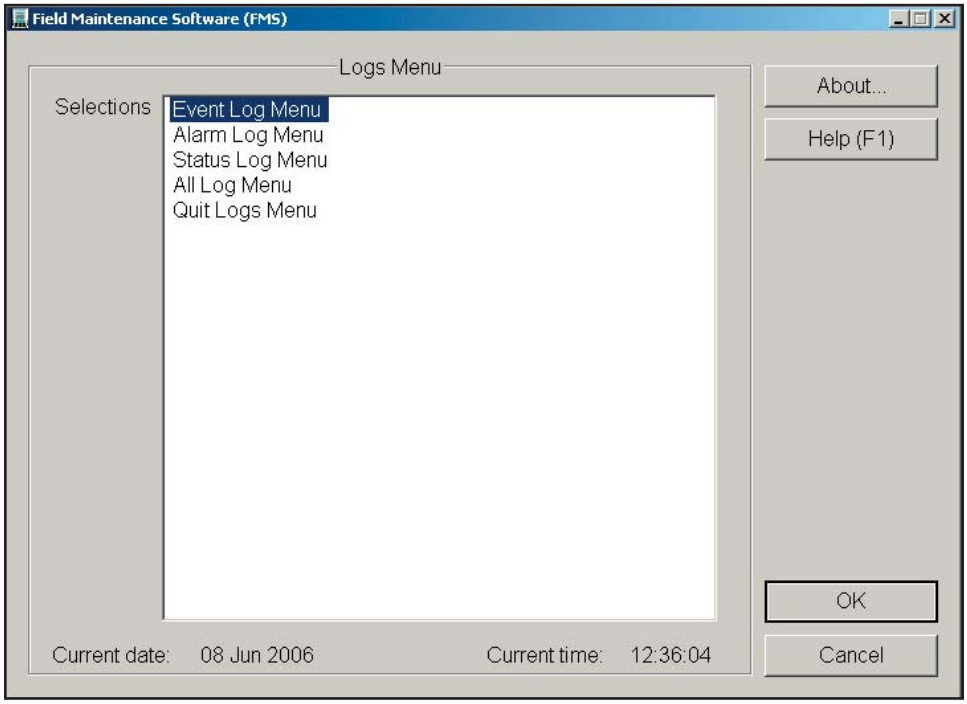
Review Log from Disk.

Print Log from Disk.

Storing a Log to File

Event, Status, Alarm, and All Log menus can be retrieved from instrument and stored to a file, displayed, and/or printed. From Main Menu, select *Logs Menu*. Logs Menu will then be displayed. See figure “Logs Menu”.

Logs Menu



Storing a Log to File (Continued)

To retrieve a log, put instrument in Maintenance Mode by simultaneously Pressing ON/OFF and MORE OPTIONS keys. Information that will be requested is as follows:

Operator Comment (optional): This information can be name of person retrieving log from Instrument or any other information, up to a maximum of 20 characters, including spaces. Information will be stored on disk along with retrieved information and will also appear on printouts.

File names are created using 3 - 9 digit serial number of instrument, as shown in “Log File Naming Conventions” figure.

To retrieve a log, put instrument in Maintenance Mode by simultaneously pressing ON/OFF and MORE OPTIONS keys. The following information will be requested:

Operator Comment (optional): This information can be name of person retrieving log from instrument or any other information, up to a maximum of 20 characters, including spaces. Information will be stored on disk along with retrieved information and will also appear on printouts.

File names are created using 3 - 9 digit serial number of instrument, as shown in following example.

S/N 123456789 creates file: *12345678.9_ _*

There are 2 trailing underline characters that are used by FMS to identify files as Event Logs, Alarm Logs, Status Logs, or All Logs. Upon entry of previous information, FMS will retrieve log, decode information, and store it on disk. If a log for an instrument with same serial number exists, FMS will prompt user to make a decision on whether to rename existing file and store it as a new file, append new data to existing file, or delete existing file and create a new one.

Log File Naming Conventions

Event Log:
12345678.9!E-Current Event Log file (Formatted)
12345678.9#E-Backup Event Log file (Formatted)
12345678.9!X-Current Event Log file (Raw)
12345678.9#X-Backup Event Log file (Raw)

Storing a Log to File (Continued)

Alarm Log:
12345678.9!A-Current Alarm Log file (Formatted)
12345678.9#A-Backup Alarm Log file (Formatted)
12345678.9!Y-Current Alarm Log file (Raw)
12345678.9#Y-Backup Alarm Log file (Raw)

Status Log:
12345678.9!S-Current Status Log file (Formatted)
12345678.9#S-Backup Status Log file (Formatted)
12345678.9!Z-Current Status Log file (Raw)
12345678.9#Z-Backup Status Log file (Raw)

All Log:
12345678.9!T-Current All Log file (Formatted)
12345678.9#T-Backup All Log file (Formatted)
12345678.9!W-Current All Log file (Raw)
12345678.9#W-Backup All Log file (Raw)

NOTE: When storing a Log to a file, if disk becomes full, user will be advised.

Displaying a Log

User can view an Event, Alarm, Status, or All Log directly from instrument or from a disk file. Viewing a log from an instrument can be done using *Retrieve Log from Instrument* option. A log that has been filed on a disk can be viewed using *Review Log from Disk* option.

Because logs for more than 1 instrument may exist on a current disk, user must select serial number for desired log on current disk. Up or down arrow keys can be used to highlight desired log file name. Press Enter key to retrieve highlighted file for viewing on screen.

Figure below gives an example of an Event Log Report. Event Log report shows Operator Comment, instrument Serial Number, Date Stored, and Time Stored.

EVENT LOG REPORT

Operator Comment:	John Doe
Instrument Serial Number:	123456789
Instrument Software version #:	5.0
FMS version #	5.0
Date Stored:	9-14-2006
Time Stored:	13:29:53

E#1 08:48:31a01Jun 945311Device Type change
E#2 08:49:05a01Jun94275BCannot home motor
E#3 08:49:36a01Jun9453332Requested Data Init
E#4 08:49:57a01Jun945331Requested Data Init

Events are displayed in chronological order. Each event will show time and date that event occurred, Event Code, affected channels, and a description of Event Code.

NOTE: When viewing Event Log Report, channel indicators are defined as follows: A, B, or C represent individual pump channels and I represents instrument or system fault. A numerical value in channel column is for factory use.

Logs Menu (Continued)

Printing a Log

User can print an Event, Alarm, or Status Log that has been stored on a disk. A log that has been filed on a disk can be printed using *Print Log From Disk* option.

Because more than 1 log of any type may exist on current disk, user must select from desired log on current disk. Up or down arrow keys can be used to highlight desired log file name. Pressing Enter key prints highlighted file.

Exiting Logs Menu

To exit Logs Menu and return to Main Menu, select *Quit Logs Menu* command and press Enter key, or press ESC key. All logs saved to disk will still be available for review or printing during next FMS session.

Exiting FMS

Turn off instrument when exiting FMS. To exit select *Quit Program* command from Main Menu and pressing Enter key returns user to Windows.

Appendix

Parameter Verification Procedures

After Instrument Configuration and Maintenance mode changes, certain parameters should be verified by exercising one of following procedures.

NOTE: On the configuration pages line items changed from factory defaults will be prefixed with an asterisk.

Verification Procedure A - Device Settings

1. Turn instrument on by pressing ON/OFF key.
2. Press MORE OPTIONS key to activate DEVICE softkey.
3. Press DEVICE softkey to display “Change Device Type” page.
4. If desired Device Type is not highlighted, press SELECT softkey as needed to highlight desired Device Type, then press ENTER softkey.
5. Press STANDARD DISPLAY key to return to Standard Display.
6. Press MORE OPTIONS key to activate CONFIG softkey.
7. Press CONFIG softkey to display “Instrument Settings” page.
8. If needed, press NEXT PAGE softkey to display parameter values page showing desired value.
9. Visually confirm desired value.
10. Press STANDARD DISPLAY key to return to Standard Display, or press ON/OFF key to turn off instrument.

Verification Procedure B - Current Settings

1. Turn on instrument by pressing ON/OFF key.
2. Press MORE OPTIONS key to activate CONFIG softkey.
3. Press CONFIG softkey to display Instrument Settings page.
4. If necessary, press NEXT PAGE softkey to display parameter showing desired value.

Parameter Verification Procedures (Continued)

Verification Procedure B - Current Settings (Continued)

5. Visually confirm desired value.

6. Press STANDARD DISPLAY key to return to Standard Display, or press ON/OFF key to turn off instrument.

Verification Procedure C -Enable DRC

1. Turn on instrument by pressing ON/OFF key.

2. Press A, B, C key as needed to activate channel information page.

3. Press MORE OPTIONS key to activate CalcOn softkey.

4. Press CalcOn softkey to activate Dose Rate Calculator Page.

5. Select a drug that is not *DRUG?* and press ENTER.

6. Verify that Concentration Unit and Dose Rate Unit can/cannot be changed.

7. Press STANDARD DISPLAY key to return to Standard Display, or press ON/OFF key to turn off instrument.

Verification Procedure D - BATLOG

1. Turn on instrument by pressing ON/OFF key.

2. Press MORE OPTIONS key twice to activate BATLOG softkey.

3. Press BATLOG softkey to display Biomed Battery History page.

4. Visually confirm desired value.

5. Press STANDARD DISPLAY key to return to Standard Display, or press ON/OFF key to turn off instrument.

Service Information

If difficulties are encountered while using FMS software, consult the following sources of information before contacting Cardinal Health, Technical Support:

- README files or package inserts accompanying product.
- Appropriate hardware manuals (instrument DFU and Service Manual, and related Service Bulletins), if a hardware problem is suspected.

Technical Support

If software fails to respond and cause cannot be determined, contact a Cardinal Health representative. Reference “General Contact Information” at the front of this document.

Provide following information:

- description of difficulty experienced
- message displayed at time of difficulty
- software version

Software Return

Contact Cardinal Health to obtain a return authorization number prior to shipment. Reference “General Contact Information” for “Customer Care” at the front of this document.

Package software (preferably in original packaging), reference return authorization number, and return to closest facility.

Trademarks

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Part Number 10014647

Field Maintenance Software
Model 286X, v5.0
Software User Manual